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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,790	10/24/2001	Daniel A. Keys	2064-181	7203
22471	7590 04/17/2003			
PATENT LEGAL DEPARTMENT/A-42-C			EXAMINER	
	COULTER, INC. BOR BOULEVARD	COUNTS, GARY W		
BOX 3100	DON DOODE VIND			
FULLERTON, CA 92834-3100			ART UNIT	PAPER NUMBER
	•		1641	5
			DATE MAILED: 04/17/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Application No. Application No. Application No. 10/032,790 KEYS ET AL Examiner Art Unit Gary W. Counts 1641							
Examiner Gary W. Counts - The MAILING DATE of this communication appears on the cover sheet with the correspondenc address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Estaksions of time may be available under the provisions of 3 CFR 1.13(a). In no event, however, may a reply be timely tilled after SN(a) (MONTHS from the miling date of this communication. If the period for reply specified above is less than thirty (30) davs, a reply while the stathory maining of this of this communication. If the period for reply specified above is less than thirty (30) davs, a reply while the stathory maining of this (10) days will be considered in the contribution of this communication. If the period for reply specified above is less than thirty (30) davs, a reply while the stathory maining of this (10) days will be considered period for reply specified of this communication. If the period for reply specified above is less than there more than the period of the state speciation to become PAND-POED (30 U S. C. § 133.) Any reply rescribed by the Office later than there more than the mailing date of this communication, even if timely filled, may reduce any some option to reply which the state of 20 TeR 1.74(b). Status Status Status Status Status A) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-31 and 43-58 is/are pending in the application. 4) Claim(s) 1-53 and 43-58 is/are pending in the application. 4) Claim(s) 1-59-16.17 and 26-31 is/are rejected. 7) Claim(s) 1-54 and 26-31 is/are rejected. 7) Claim(s) 1-54 and 26-31 is/are rejected. 7) Claim(s) 1-54 and 26-31 is/are rejected. 10) The drawing(s) filed on 1-154 and 26-31 is/are rejected. 11) The proposed drawing correction filed on 1-154 and 26-31 is/are rejected. 12) The propos	•	Application No.	Applicant(s)				
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The MAILING DATE of this communication appears on the cover sheet with the correspondenc address — Period for Reply' A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ② MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Edetections of time may be available under the provision of 3°C FR 1.13(b). In one event, however, may a reply be timely filled of the SIX (6) MONTHS from the mailing date of this communication. I NO period for reply is qualified under the provision of 3°C FR 1.13(b). In one event, however, may a reply be timely filled of the SIX (6) MONTHS from the mailing date of this communication. I NO period for reply is qualified users the maximum evaluation previous thing your addition state (5) (6) MONTHS from the mailing date of this communication. I NO period for reply is qualified users the mitroe morphism start his mailing date of this communication, even if timely (8) duty may reduce any event of the supplication to become ABANDONED (810 VS.C. § 133). Any reply received by the Office acts than three mailing date of this communication, even if timely (8) duty reduce any event plants the mailing date of this communication, even if timely (8) duty reduce any event plants the mailing date of this communication, even if timely (8) duty reduce any event plants the mailing date of this communication, even if timely (8) duty reduce any event plants the plants of the communication of the communication and event plants the plants of the communication of the communication and event plants the mailing date of this communication. Status 1)② Responsive to communication (8) filled on 24 March 2003. 2a) This action is FINAL. 2b) March 2003. 2b) This action is FINAL. 2b) March 2003. Claim(s) 1-31 and 43-58 is/are pending in the application. 4a) Of the above claim(s) 2-4.10-15.18-25 and 43-58 is/are withdrawn from consideration. 5] Claim(s) 1-32 and 43-58 is/are pending in the application. 4b) Claim(s) 1-32 and 43-58 is/are allowed. 6b) Claim(s) 1-32 and 43-58 is/are allowed. 6c) Claim(s) 1-	Office Action Summary	Examiner	Art Unit				
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THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled offers SIX (6) MONTHS from the malling date of this communication. If the promot for reply specified above is less than their (30) days, a reply within the solution reply reply and their (30) days and the conducted timely. Failure to reply valinity days are the solution of the solution of their (30) days and the communication. Failure to reply visitin the saft or extended period for reply visit. by statute, cause the application to become ABANDONED (35 U.S.C. § 139). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filled, may reduce any canned patent term adjustment. See 37 CFR 1.734(b). Status 1) Responsive to communication(s) filled on 24 March 2003 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-31 and 43-58 is/are pending in the application. 4a) Of the above claim(s) 2-4.10-15.18-25 and 43-58 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1,5-9.16.17 and 26-31 is/are rejected. 7) Claim(s) are subjected to by the Examiner. Application Papers 9) The specification is objected to by the Examiner. Application Papers 9) The proposed drawing correction filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is/are: a) accepted or b) objected to by the Examiner: If approved, corrected drawings are required in reply to this Office action. 12) The coath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119							
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13) Acknowledgment is made on a claim for domestic priority under 33 0.3.C. 99 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 4) Interview Summary (PTO-413) Paper No(s) Notice of Informal Patent Application (PTO-152) 6) Other:	2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal I					

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 5-31 and species, cytokines in Paper No. 4 is acknowledged. The traversal is on the ground(s) that Groups I, II, and III do not define independent and distinct inventions. That multiple searches would not be required and that no additional burden on the Examiner would result from examining the 3 additional claims of Groups II and III with those of Group I This is not found persuasive because while searches would be expected to overlap, there is no reason to expect the searches to be coextensive. Further, the additional limitations in Groups II and III would require an additional literature search. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1, 5-9, 16, 17 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sufficient" in claim 1 is a relative term which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claims 17 is vague and indefinite because of the use of acronyms: i.e. IL-, Ron, VEGF, GMCSF etc............ Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 5. Claims 1, 5-9, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Herron et al (US 6,287,871).

Herron et al disclose a method for detecting the concentration of an analyte of interest. Herron et al disclose that the method can detect multiple analytes. Herron et al disclose conducting a fluorescent assay to determine the concentration of analyte (col 3, -col 4). Herron et al disclose employing a computer system comprising a CCD camera (col. 7, line 56 – col. 8, line 67) to detect light signals. Herron et al disclose a solution with a known minimum analyte concentration is analyzed and a solution with a known maximum concentration is analyzed and that the process is repeated with progressively larger known analyte concentrations. The photodetection means determines corresponding fluorescence intensities. Herron et al disclose that the

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computer calculates the concentration of the analyte of interest (col 15 – col 16).

Herron et al disclose that the photodetectors (CCD) could be simultaneous or sequential (col 14).

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of Lehmann et al (US 5,939,281).

Herron et al differ from the instant invention in failing to teach the assay is to determine the concentration of a cytokine.

Lehmann et al disclose specific binding reagents, such as antibodies, for detecting the presence or amount of cytokines in a test sample.

It would have been obvious to one of ordinary skill in the art to use the cytokine specific antibodies taught by Lehmann et al in the method of Herron et al because Herron et al is generic with respect to the analyte that is to be detected and one would use the appropriate reagent, i.e. antibody to detect the desired analyte, in this case cytokines.

8. Claim 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of Campbell et al (US 4,946,958).

See above for teachings of Herron et al.

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Herron et al differ from the instant invention in failing to teach the light signal is a chemiluminescent light signal.

Campbell et al disclose a chemiluminescent label used in analysis, assay or location of proteins, polypeptides and other substances of biological interest (col. 1). Campbell et al disclose that the use of this chemiluminescent label provides a means of improving the sensitivity of measurement of proteins and polypeptides or other substances of biological interest by one to two orders of magnitude by comparison with existing techniques (col. 7).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a chemiluminescent label as taught by Campbell et al into the method of Herron et al because Campbell et al shows that this chemiluminescent label provides a means of improving the sensitivity of measurement of proteins and polypeptides or other substances of biological interest by one to two orders of magnitude by comparison with existing techniques.

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of McMillan et al (US 6,057,163).

See above for teachings of Herron et al.

Herron et al differ from the instant invention in failing to specifically teach the well is a multi-well microtiter plate.

McMillan et al disclose the use of a microwell plate to detect luminescence or fluorescence in a sample. McMillan et al disclose that the use of the microwell plate

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provides a quantitation system for detecting the amount of light emitted by a plurality of samples hold and provides for increased throughput (col 2 & 4).

It would have been obvious to one of ordinary skill in the art to incorporate a microwell plate as taught by McMillan et al into the method of Herron et al because McMillan et al disclose that the use of the microwell plate provides a quantitation system for detecting the amount of light emitted by a plurality of samples hold and provides for increased throughput.

Conclusion

- 10. No claims are allowed.
- 11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,337,472 Garner et al disclose the use of a CCD camera in clinical diagnostics/prognostics and basic biomedical research.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts

I any Count

Examiner

Art Unit 1641

April 7, 2003

CHRISTOPHER L. CHIN PRIMARY EXAMINER GROUP 1800-/64/

Christyl L. Chin

4/15/03